

#91181631  
8/23/02

PATENT  
ATTORNEY DOCKET NO.: 044921-5029-01-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: William MUNGER *et al.* )  
Application No.: 09/960,706 ) Group Art Unit: 1631  
Filed: September 24, 2001 ) Examiner: Moran, M.  
For: IDENTIFYING DRUGS FOR AND DIAGNOSIS )  
OF BENIGN PROSTATIC HYPERPLASIA )  
USING GENE EXPRESSION PROFILES )

RECEIVED

Commissioner for Patents  
Washington, D.C. 20231

AUG 23 2002

TECH CENTER 1600/2900

Sir:

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449. To the best of Applicants' knowledge, this Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits in accordance with 37 C.F.R. § 1.97(b)(3). In the event that a first Office Action on the merits has been mailed, this Information Disclosure Statement is also being filed not more than three months after the first citation by a foreign patent office of each item of information on the accompanying form PTO-1449 in a counterpart foreign application in accordance with 37 C.F.R. § 1.97(e)(1). Accordingly, Applicants do not believe that a fee is due for filing this paper.

Pursuant to 37 C.F.R. § 1.97(d)(1), the references are not included with this submission, having been provided in prior application 09/873,319. Applicants respectfully request that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached form. An International Search Report in the corresponding International Application citing these documents and setting forth the relevance thereof is also attached.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If it should be determined that any of the listed documents


do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

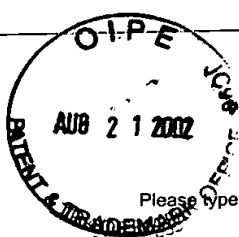
**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. §1.136(a)(3).

Respectfully submitted,  
**MORGAN, LEWIS & BOCKIUS LLP**

August 21, 2002

  
\_\_\_\_\_  
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Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (10-96)  
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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)  Sheet 1 of 1		<b>Complete if Known</b>	
		Application Number	09/960,706
		Filing Date	9/24/2001
		First Named Inventor	William MUNGER
		Group Art Unit	1631
		Examiner Name	Moran, M.
		Attorney Docket Number	44921-5029-01-US

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U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,763,429		Bishop et al.	6/9/1998	
		5,882,864		An et al.	3/16/1999	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>8</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Bubendorf, L et al. Survey of gene amplifications during prostate cancer progression by high-throughput fluorescence in situ hybridization on tissue microarrays. (1999) Cancer Research 59:803-806.	
		Bubendorf, L et al. Hormone therapy failure in human prostate cancer: analysis by complementary DNA and tissue microarrays. (1999) J. Nat. Cancer Inst. 91(20):1758-1764.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 44921-5029WO	<b>FOR FURTHER ACTION</b>	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US01/24708	International filing date ( <i>day/month/year</i> ) 07 August 2001 (07.08.2001)	(Earliest) Priority Date ( <i>day/month/year</i> ) 07 August 2000 (07.08.2000)
Applicant GENE LOGIC, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (See Box II).

4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. \_\_\_\_\_



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/24708

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-3

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/24708

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : C12Q 1/68

US CL : 435/6

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6; 514/168

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,763,429 A (BISHOP et al) 9 June 1998(09.06.1978), see entire document.	1-3
X	US 5,882,864 A (AN et al) 16 March 1999(16.03.1999), see entire document.	1-3
X	Bubendorf et al. Survey of Gene Amplifications during Prostate Cancer Progression by High-Throughput Fluorescence in Situ Hybridization on Tissue Microarrays. Can. Res. Issued 15 February 1999, Volume 59, pages 803-806, see entire document.	1-3
X	Bubendorf et al. Hormone Therapy Failure in Human Prostate Cancer: Analysis by Complementary DNA and Tissue Microarrays. J. Nat. Can. Inst. Issued 20 October 1999, Volume 91, Number 20, pages 1758-1764, see entire document.	1-3

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 27 March 2002 (27.03.2002)	Date of mailing of the international search report 09 JUL 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer <i>Felicia D. Roberts for</i> Charming S. Mahatan Telephone No. (703) 308-0196

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/24708

### BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

In a telephone conversation with Michael S. Tuscan, March 15, 2002, to determine whether applicants' elected additional groups it was pointed out that the original lack of unity contained an error whereby Group 1 (claim(s) 1-3), drawn to gene profiling of benign prostatic hyperplasia, was inadvertently omitted. It is hereby agreed upon that the lack of unity requirement be modified by the addition of Group 1. Therefore, the original Group 1-755 is now Group 2-756, the original Group 756-1510 is now Group 757-1511, etc. Applicants' elected newly modified Group 1 (claim(s) 1-3), and no additional groups.

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group 1 (claim(s) 1-3), drawn to gene profiling of benign prostatic hyperplasia (newly modified).

Groups 2-756 (claim(s) 1-7), drawn to a method of identifying an agent that modulates the onset or progression of benign prostatic hyperplasia in cells based on expression of SEQ ID NO X, wherein X is anyone of SEQ. ID. Nos: 1-755. For example,

If Group 2 is elected, this correlates with SEQ ID NO: 1.

Groups 757-1511 (claim(s) 8-12), drawn to a method of diagnosing the onset or progression of benign prostatic hyperplasia in a subject based on expression of SEQ ID NO X, wherein X is anyone of SEQ. ID. Nos: 1-755. For example,

If Group 757 is elected, this correlates with SEQ ID NO: 1.

Groups 1512-2266 (claim(s) 13-17), drawn to a method of differentiating prostatic hyperplasia from prostate cancer based on expression of SEQ ID NO X, wherein X is anyone of SEQ. ID. Nos: 1-755. For example, If Group 1512 is elected, this correlates with SEQ ID NO: 1.

Groups 2267-3021 (claim(s) 18-31), drawn to an oligonucleotide probe of SEQ ID NO X, wherein X is anyone of SEQ. ID. Nos: 1-755. For example,

If Group 2267 is elected, this correlates with SEQ ID NO: 1.

Groups 3022-3776 (claim(s) 32-43), drawn to a computer-system comprising a database of information pertaining to SEQ ID NO X, wherein X is anyone of SEQ. ID. Nos: 1-755. For example,

If Group 3022 is elected, this correlates with SEQ ID NO: 1.

Groups 3777-4531 (claim(s) 44-48), drawn to a method of monitoring treatment in a patient based on gene expression of SEQ ID NO X, wherein X is anyone of SEQ. ID. Nos: 1-755. For example,

If Group 3777 is elected, this correlates with SEQ ID NO: 1.

Group 4532 (claim(s) 49 and 50), drawn to a method of analysing gene expression results by implementing an algorithm.

The inventions listed as Groups 1-4532 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claimed methods produce different products and/or different results which are not coextensive and which do

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/24708

not share the same technical feature; identification of a compound, diagnosing BPH, differentiating from cancer, an oligonucleotide probe, computer-system, monitoring treatment, and analysis with an algorithm. Furthermore, the claims are directed to different genes corresponding to SEQ ID Nos: 1-755. Each of these genes are separate entities which encodes different proteins with different activities, binding reactions, antibody recognition, etc. and thus each has its own special technical feature. Thus, in summary, each of Groups 1-4532 are directed to different special technical features and thus support this lack of unity.

### Continuation of B. FIELDS SEARCHED Item 3:

US PAT FULL, COMPUSCENCE, BIOSIS, BIOCOMMERCE, CAPLUS

search terms: benign prostatic hyperplasia, gene expression, cell, drug, microarray, compare